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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/049,874 | 07/01/2002 | Jean-Yves Godard | 146.1381 | 2338 |

20311 7590 05/29/2003

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EXAMINER

KIFLE, BRUCK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1624 | 8 |

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|---|---------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/049,874 | Applicant(s) Godard et al. |
| | Examiner Bruck Kifle, Ph.D. | Art Unit 1624 |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | |
| Period for Reply | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | |
| - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | |
| Status | | |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jul 1, 2002</u> | | |
| 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | |
| Disposition of Claims | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-8, 14, and 15</u> is/are pending in the application. | | |
| 4a) Of the above, claim(s) _____ is/are withdrawn from consideration. | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>1-8, 14, and 15</u> is/are rejected. | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | |
| 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement. | | |
| Application Papers | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | |
| 13) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input checked="" type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input checked="" type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. | | |
| 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | |
| 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | |
| Attachment(s) | | |
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>1</u> | | |
| 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | | |
| 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | | |
| 6) <input type="checkbox"/> Other: | | |

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Claim Rejections - 35 USC § 112

Claims 1-8, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The term "agglomerate" means two or more molecules together which is always the case.

Applicants intention is unclear. A clarification is required.

ii) It is unclear what degree of sphericity is required. Is an absolute geometrically perfect sphere required?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Graul et al. (Drugs of the Future 1998, 23(6): 591-597) or Agouridas et al (EP 680 967). The references teach the compound RN 173838-31-8 (i.e., telithromycin) instantly claimed.

MPEP 2112 states "The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard

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to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.”

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. “There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.” *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977): Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.

In the instant case, there is no way one can say for sure whether telithromycin is not present in the claimed particle size or “spherical agglomerate” form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

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The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

May 28, 2003


Bruck Kifle
Primary Examiner
Art Unit 1624